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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,008	SAS ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 10* is/are pending in the application.

4a) Of the above claim(s) *4 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted September 25, 2007 is acknowledged.

The claims have been examined insofar as they read on the elected invention and species in the reply filed on March 19, 2007. Claim 10 was withdrawn from the consideration as drawn to nonelected invention. Claim 10 does not read on the elected invention, (X1, X2, Y and Z are oxygen) as the –O-O- linkage is substituted with other atoms. Note claim 10 was improperly listed as rejected claim in the prior office action.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qian et al. (J. Traditional Chinese Medicine vol. 2, No. 4, pp 272-276), Efferth et al. (IDS), Zheng et al. (IDS), Venugopalan et al. (EP 0 456 149 A1, IDS), and Li et al. (CN 1122806 A), and in further view of Crooks et al. (US 6,677,347).

3. Qian et al. teaches that artemisinin (qinghaosu) have immunologic and antiviral activity. It augments cell-mediated immunity. See, particularly the Abstract. Efferth et al. teaches that artesunate is effective against cytomegalovirus, see, particularly the abstract; Zheng et al. also teaches that artemether is effective for suppressing the epidemic hemorrhagic fever virus. See, particularly, the abstract. Venugopalan et al. teaches method of treating viral infection

comprising administering artemisinin compounds. See, particularly the claims. Li et al. teaches artemisinin derivatives are known to be useful as anti-tumor, antiviral and anti-parasitic agents. See, particularly the abstract. It is noted that the artemisinin derivatives employed by Venugopalan et al and Li et al. is not within the scope of artemisinin compounds defined herein, but, the compounds all have the core structure of artemisinin. The cited references as a whole have fairly teach or suggest that compounds with the core structure of artemisinin have a broad spectrum of antiviral, anti-tumor, anti-parasitic activity and have immunologic augmenting activity.

4. The prima references as a whole do not teach expressly the employment of the artemisinin compounds for treatment of hepatitis C infection, alone, or with interferon.

5. However, Crooks et al. teaches that compound that augments cell-mediated immunity, as well as interferon, are useful for treatment of tumors and viral infections, such as hepatitis C infection. See, particularly, col. 19, line 39 to col. 20, line 54.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ artemisinin, alone, or with interferon, for the treatment of hepatitis C infection.

A person of ordinary skill in the art would have been motivated to employ artemisinin, alone, or with interferon, for the treatment of hepatitis C infection because artemisinin are antiviral agents useful against a broad spectrum of virus and are known to augment cell-mediated immunity and compounds augmenting cell-mediated immunity, as well as interferon, are useful for treating viral infections, such as hepatitis C infection. The further employment of interferon with artemisinin would have been obvious because both agents are known to be useful for

treatment of viral infections and it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known antiviral agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069.

Response to the Arguments

Applicants' amendments and remarks submitted September 14, 2007 have been fully considered, but are not persuasive.

6. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, the cited references disclosed that artemisinin is known to have immunologic and antiviral activity. It augments cell-mediated immunity and is known to be useful against a wide spectrum of virus. The cited references also show that augmenting cell-mediated immunity is particularly known to be useful for treatment of hepatitis C viral infection. Therefore, it would have been obvious to one of ordinary skill in the art to employ artemisinin for treatment of hepatitis C.

7. In response to applicant's argument that artemisinin shows a "concentration dependant effect in a hepatitis C replicon model", the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for

patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

8. The instant claims are directed to affecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (treating viral infection) for the compounds, e.g., artemisinin, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds, i.e., treatment of viral infection, is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

9. The pending claims contain subject matter drawn to an invention nonelected with traverse in the reply filed on March 19, 2007. A complete reply to the final rejection must include amendments of the claims so that the pending claims are limited to elected invention, i.e., for the compounds, wherein X1, X2, Y and Z are oxygen.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617